

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

REC'D 10 MAR 2006
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Applicant's or agent's file reference PH03104-PCT	FOR FURTHER ACTION																	
See Form PCT/IPEA/416																		
International application No. PCT/GB2004/005410	International filing date (day/month/year) 23.12.2004	Priority date (day/month/year) 23.12.2003																
International Patent Classification (IPC) or national classification and IPC INV. B01J41/04 B01J20/32 C08G61/08 C09D165/00																		
Applicant HAMMERSMITH IMANET LTD et al.																		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> <i>sent to the applicant and to the International Bureau</i> a total of sheets, as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																		
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/> Box No. I</td> <td style="width: 85%;">Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand 21.10.2005	Date of completion of this report 09.03.2006																	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Meier, S Telephone No. +49 89 2399-8312																	
																		

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-27 as originally filed

Claims, Numbers

1-27 as originally filed

Drawings, Sheets

1/11-11/11 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

- The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
- This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
 - the entire international application,
 - claims Nos. 19, 20
 - because:
 - the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
 - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - no international search report has been established for the said claims Nos. 19, 20
 - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard
the computer readable form	<input type="checkbox"/> has not been furnished
	<input type="checkbox"/> does not comply with the standard
 - the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
 - See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-18
	No: Claims	21-23
Inventive step (IS)	Yes: Claims	1-18
	No: Claims	21-27
Industrial applicability (IA)	Yes: Claims	1-18, 21-27
	No: Claims	-

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Reference is made to the following documents:

D1: WO 00/73782 A (MERCK PATENT GMBH; BUCHMEISER, MICHAEL, RUDOLF; SINNER, FRANK, MICHAEL)

D2: MICHAEL R. BUCHMEISER: "Application of metathesis in heterogeneous catalysis and separation sciences" JOURNAL OF MOLECULAR CATALYSIS A: CHEMICAL, vol. 190, 2002, pages 145-158, XP002323907

D3: JÜRGEN FALBE, MANFRED REGITZ: "Römpf Chemie Lexikon" 1990, GEORG THIEME VERLAG, STUTTGART NEW YORK, XP002323961

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1.1 cf. reasoning on separate sheet PCT/ISA/210 of the International Search Report.
- 1.2 The subject matter claimed in independent claim 19 of the present application is well known and it just represents e.g. a plastic tube having a certain diameter. Since any surface of a polymer article e.g. of a polymer tube is somehow different (e.g. by surface oxidation during manufacture, etc.) from the layers beneath the surface any polymer tube having a diameter of less than 2 mm like a catheter will fulfill the requirement of a "*inner surface being coated with a polymer substrate for a solid phase physical or chemical process*", in particular as the present claim 19 is silent concerning the nature of the polymer which coats the inner surface of the device.
- 1.3 Present claim 20 relates to a product defined by reference to a desirable characteristic or property, namely "*adapted for carrying out a solid phase radiochemical process*". On page 4, lines 14-21 specific measures are mentioned in order to adapt the device, however, these measures are not mentioned in dependent claim 20 of the present application.
- 1.4 Therefore, claims 19-20 cover all products having this characteristic or property, whereas the application provides support withing the meaning of Art. 6 PCT and/or disclosure withing the meaning of Art. 5 PCT for only a very limited number of such products. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful examination over the whole of the claimed scope is impossible.
- 1.5 Independent of the above reasoning, claim 19 and in particular claim 20, also lacks

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clarity (Art. 6 PCT). An attempt is made to define the product by reference to a "*result to be achieved*", which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

1.6 For these reasons claims 19 and 20 have been excluded from search and do thus not form the subject of an International Preliminary Examination (R. 66.1(e) PCT).

Re Item VIII

Certain observations on the international application

2. Clarity - Art. 6 PCT

2.1 The term "*microfabricated device*" as used in claims 2, 4 and 18 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature/s to which it refers, thereby rendering the definition of the subject-matter of said claims unclear, Art. 6 PCT. In particular, this term has not been limited to the device described on page 3, lines 8-11.

2.2 Claim 5 does not meet the requirements of Art. 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the *result to be achieved*, namely "*the device is adapted to carry out a solid-phase radiochemical process*", which merely amounts to a statement of the underlying problem, without providing the technical features (e.g. the specific polymers employed) necessary for achieving this result (cf. also item 1.3 of this report).

2.3 Expressions like "*about*" or a similar term as used in claims 2, 19 and on page 2, line 24; page 3, lines 30 and 32; page 13, line 24 of the present application are contrary to the requirements of PCT-Guidelines II 5.38.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Novelty

2.1 Therefore, the now independent claim 21 of the present application claims:

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- a) A device comprising
- b) a microfabricated device or a reaction vessel with an internal diameter of less than 2 mm
- c) wherein the internal surface is coated with a ROMP polymer.

2.2 The independent claim 1 of the present application claims:

- a) A method of coating the internal surface of a device with a polymer, the process comprising the steps of:
- b) introducing into the device a solution of one or more monomers in a suitable solvent
- c) introducing a flow of an inert gas through the device; and
- d) initiating polymerisation of the monomer solution.

2.3 Document **D1** discloses a) a monolithic support material comprising b) a reaction vessel like a HPLC column having a diameter of 200 µm c) wherein the inner surface of said vessel has been modified with a monomer which is suitable for metathesis polymerisation and the polymerisation on these groups. d) Several crosslinking agents have also been employed. e) Monomers as used in the present application have been employed, except for tertiary amine ROMP monomers. f) All reactions have been carried out under an inter atmosphere. g) These monolithic support materials can be used for ion exchange chromatography. h) A process for the production of the monolithic support material which encompasses the step of "*introducing a flow of an inert gas*" has not been disclosed (abstract; page 3, line 9-page 8, line 8; claims 1, 4, 5; Fig. 1a, 1b, 2; example A2).

2.4 Therefore, claims 21-23 do not fulfill the requirements of Art. 33(1) PCT since they are not novel over the prior art document **D1** in the sense of Art. 33(2) PCT.

2.5 The same applies to document **D2** (the whole document):

2.6 **NB:** The wording of the present product claims 21-23 does not exclude the presence of a continuous matrix within the device. It only requires that the inner surface is coated with a ROMP polymer. This requirement has been fulfilled in the prior art document **D1** and **D2**. The present product claims are silent concerning a hollow article.

3. Inventive Step

3.1 **D1** is considered as closest prior art document.

3.2 The difference between **D1** and claims 24-27 of the present application is the use of

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tertiary amine ROMP polymers as anion exchangers.

- 3.3 However, the use of such functional groups for anion exchangers is generally known in the art (cf. e.g. **D3**).
- 3.4 Therefore, the person skilled in the art would by combination of the teaching of **D1** on the ion exchange ability of the ROMP resins (page 6, lines 15-23) and the general knowledge on the use of tertiary amine polymers for anion exchanger, apply the same method as claimed by the subject matter of claims 24-27 of the present application.
- 3.5 Therefore, claims 24-27 of the present application do not fulfill the requirements of Art. 33(1) EPC, since they do not involve an inventive step in the sense of Art. 33(3) PCT.
- 3.6 Since claims 21-23 are not novel over the prior art documents **D1** and **D2** as outlined under items **2.1-2.5** they cannot involve an inventive step in the sense of Art. 33(3) PCT and thus do not meet the requirements of Art. 33(1) PCT.
- 3.7 Claims 1-18 of the present application are considered to fulfill the requirements of Art. 33(3) PCT since there are no hints in **D1** and/or **D2** which would suggest to the person skilled in the art to use a flow of inert gas for the fabrication of a polymer coated internal surface of a device.

4. Industrial Applicability

- 4.1 The subject matter of claims 1-18 and 21-27 is industrial applicable.